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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/171,885	10/28/98	CUBICCIOTTI	R BDA-0038

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HM12/0523

EXAMINER

WARE, T

ART UNIT	PAPER NUMBER
1615	12

DATE MAILED: 05/23/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

## Office Action Summary

Application No. 09/171,885	Applicant/ Cubicciotti
Examiner Todd D. Ware	Group Art Unit 1615



Responsive to communication(s) filed on Mar 14, 1900

This action is **FINAL**.

Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle* 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

### Disposition of Claim

Claim(s) 13-29 is/are pending in the application.  
Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 Claim(s) \_\_\_\_\_ is/are allowed.  
 Claim(s) 13-29 is/are rejected.  
 Claim(s) \_\_\_\_\_ is/are objected to.  
 Claims \_\_\_\_\_ are subject to restriction or election requirement.

### Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.  
 The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.  
 The proposed drawing correction, filed on \_\_\_\_\_ is  approved  disapproved.  
 The specification is objected to by the Examiner.  
 The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).  
 All  Some\*  None of the CERTIFIED copies of the priority documents have been  
 received.  
 received in Application No. (Series Code/Serial Number) \_\_\_\_\_  
 received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

### Attachment(s)

Notice of References Cited, PTO-892  
 Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_  
 Interview Summary, PTO-413  
 Notice of Draftsperson's Patent Drawing Review, PTO-948  
 Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

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### **DETAILED ACTION**

Receipt of request for extension of time (granted) and request for filing under 37 CFR 1.53(d) (granted) both filed 3-14-00 is acknowledged. Claims 1-12 have been canceled and new claims 14-29 have been added. Claims 13-29 are pending.

#### ***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 13-29 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Morgan, Jr. et al. (5,106,951; hereafter '951).

'951 discloses drug/carrier complexes and a method of administering a drug via a drug/carrier complex where a drug binds to a polymeric carrier to form a prodrug complex that is capable of allowing drug dissociation from the polymeric carrier such that the drug retains its ability to bind to a site on or within a target cell. Since '951 states that the drug's ability to bind to a higher affinity site on or within the target cell is retained (abstract; C4, L43-C5, L25; C8, L30-40; C18, L43-48), the conjugate of '951 binds preferentially to the "pathophysiologic receptor" (the higher affinity site on or within the target cell). '951 also discloses that the drug-conjugate is not exposed to derivatization conditions that might compromise the potency of the

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drug (i.e. the drug is immobilized and is protected from metabolism which would increase its half-life over administration of the drug alone) (C4, L43-50). '951 further discloses that targeting proteins may be attached to the conjugate.(C7, L10-19, 30-37). The carriers of '951 may also bind more than one drug (C10, L62-66). The methods used to identify the conjugate are *not* considered patentably distinct as they are intended use limitations. Furthermore, the antibodies of '951 would be readily identifiable by the instant methods.

***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 13-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Morgen, Jr. et al. (5,106,951; hereafter '951).

'951 teaches drug/carrier complexes and a method of administering a drug via a drug/carrier complex where a drug binds to a polymeric carrier to form a prodrug complex that is capable of allowing drug dissociation from the polymeric carrier such that the drug retains its ability to bind to a site on or within a target cell. Since '951 states that the drug's ability to bind to a higher affinity site on or within the target cell is retained (abstract; C4, L43-C5, L25; C8, L30-40; C18, L43-48), the conjugate of '951 binds preferentially to the "pathophysiologic

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receptor" (the higher affinity site on or within the target cell). '951 also discloses that the drug-conjugate is not exposed to derivatization conditions that might compromise the potency of the drug (i.e. the drug is immobilized and is protected from metabolism which would increase its half-life over administration of the drug alone) (C4, L43-50). '951 further discloses that targeting proteins may be attached to the conjugate.(C7, L10-19, 30-37). The carriers of '951 may also bind more than one drug molecule (C10, L62-66). The methods used to identify the conjugate are considered patentably distinct as they are intended use limitations. Furthermore, the antibodies of '951 would be readily identifiable by the instant methods.

'951 does not specifically state that the carriers of '951 may bind multiple drugs wherein the drugs are different. '951 does state that the carriers have multiple drug-binding regions capable of binding multiple drug molecules. Therefore, it would be obvious to one skilled in art at the time of the invention to design the conjugates of '951 wherein the domains would be different would be capable of binding more than one drug where the drugs are different with the expectation that administering more than one drug to treat a condition would result in an additive treatment effect with the motivation of protecting the drug against metabolism or other factors that might reduce potency.

### *Conclusion*

5. Currently, no claim is allowed. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Todd Ware whose telephone number is

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(703) 305-1700. The examiner can normally be reached on Monday through Friday from 8 AM to 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235 or 308-1234.

*GSK*  
Gollamudi S. Kishore, PhD  
Primary Examiner  
Group 1400

tw

5/17/00